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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/077,214	05/26/1998	WALTER SCHMIDT	0652.1710000	5745

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STERNE KESSLER GOLDSTEIN & FOX
1100 NEW YORK AVENUE NW
SUITE 600
WASHINGTON, DC 200053934

EXAMINER	
SCHWADRON, RONALD B	
ART UNIT	PAPER NUMBER
1644	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/077,214	Applicant(s) Schmidt et al.
	Examiner Ron Schwadron	Art Unit 1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Dec 21, 2001* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *36-70* is/are pending in the application.

4a) Of the above, claim(s) *37, 41, 45-47, and 51-68* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *36, 38-40, 42-44, 48-50, 69, and 70* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

1. The request filed on 12/21/2001 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/077214 is acceptable and a CPA has been established. An action on the CPA follows. Claims 36,38-40,442-44,48-50,69,70 are under consideration. Claim 36 has been amended.

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 69 and 70 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is no support in the specification as originally filed for the method steps recited in claim 69 or 70. Regarding the specification, pages 22 and 24, said pages disclose partially conjugated polylysine and polylysine/transferrin conjugate, but do not disclose the scope of the claimed invention (eg. partially conjugated polycation, wherein the polycation is not polylysine and polycation/transferrin conjugate, wherein the polycation is not polylysine). In addition, the cited pages of the specification appear to disclose partially conjugated polylysine conjugated to a protein and not any molecule per se. There is no written description of the scope of the claimed invention in the specification as originally filed (e.g. the claimed invention constitutes new matter).

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 69 and 70 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 69 is indefinite in the recitation of "partially conjugated with another molecule" because it is unclear what this means or encompasses. It is unclear if this refers to a particular method of conjugation (eg. partial versus completely attached to the recipient molecule) and it is unclear as to what parameters would be encompassed by a "partially" versus completely attached molecule. Claim 69 lacks antecedent basis in the recitation of "process of claim 36" because claim 36 is drawn to a product, not a process.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 36,38-40,42-44,48-50,69,70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nair et al. in view of Fearon et al., Townsend et al., Van Der Bruggen et al. and prior art disclosed in the specification (see page 3).

Nair et al. disclose use of an organic polycation (eg. cationic liposomes) to deliver an MHC class I antigen to tumor cells (see abstract). The organic polycation used by Nair et al. contains polylysine conjugated to another molecule (see abstract and page 238, second column, last paragraph). Nair et al. teach that said method is an efficient means of sensitizing target cells for CTL lysis in the context of MHC class I (see page 242, last sentence). Nair et al. do not disclose human tumor cells treated to express influenza virus peptide in the context of HLA class I. Fearon et al. teach a tumor vaccine wherein tumor cells are transfected with the gene encoding HA (see entire paper). HA is a viral antigen. Townsend et al. teach that influenza HA or NP peptides are recognized by CTL in the context of MHC class I. Van Der Bruggen et al. teach MHC class I restricted tumor antigens and that such antigens can be used to provoke CTL in vivo (see page 15, second paragraph). Van Der Bruggen et al. teach that said peptides can be delivered by vector (to infect APC) or by direct administration of the peptide to APC (see page 15, second paragraph). The art recognizes that tumors express numerous different tumor associated antigens (see prior art disclosed in specification, page 3). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Nair et al. disclose use of an organic polycation (eg. cationic liposomes containing polylysine) to deliver an MHC class I antigen to tumor cells, Fearon et al. teach a tumor vaccine wherein tumor cells are transfected with the gene encoding HA while Van Der Bruggen et al. teach MHC class I restricted tumor antigens and that such antigens can be used to provoke CTL in vivo. In view of the fact that the cells disclosed by Nair et al. were treated with intact protein, said cells would have been expected to present multiple different peptides representing different epitopes derived from said molecule. It would also be expected that HA would encode a variety of different epitopes that would bind different HLA molecules found on MHC antigen heterozygous human tumor cells. One of ordinary skill in the art would have been motivated to do the aforementioned because of the demonstration by Fearon et al. of the use of HA transfected tumor cells as a tumor vaccine, while Nair et al. teach that their method is an efficient means of sensitizing target cells for CTL lysis in the context of MHC class I. Regarding the "allogeneic" tumor vaccine limitation, the recitation of an intended use (eg. delivery to an allogenic host) carries no patentable weight in this product claim. Regarding the limitation of claim 70, the

recitation of a method wherein the claimed product is made carries no patentable weight in the instant product claims because the claimed product appears to be the same irregardless of how it is made (eg. loaded with peptide via incubation with polylysine versus loaded with peptide via incubation with transferrin/polylysine).

Regarding applicants comments about Nair et al., the recitation of an intended use carries no patentable weight in this product claim. The claimed human cells could be used in in vitro assays. Nair et al. disclose use of an organic polycation (eg. cationic liposomes) to deliver an MHC class I antigen to tumor cells (see abstract). Nair et al. teach that said method is an efficient means of sensitizing target cells for CTL lysis in the context of MHC class I (see page 242, last sentence). In addition, Fearon et al. establish that the art recognized that antigen loaded tumor cells could be used in in vivo models (see abstract). Regarding applicants comments about the specification, both Nair et al. and Fearon et al. teach that the immunogenicity of tumor cells can be increased by adding additional exogenous antigens to said tumor cells. One of ordinary skill in the art at the time the invention was made would have a reasonable expectation of success of producing the claimed invention because Fearon et al. teach use of HA transfected tumor cells as a tumor vaccine, while Nair et al. teach that their method is an efficient means of sensitizing target cells for CTL lysis in the context of MHC class I.

8. No claim is allowed.

9. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Group 1600 at (703) 308-4242.

10. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Monday through Thursday from 7:30 to 6:00. A message may

be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Ms Christina Chan can be reached on (703) 308-3974. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP ~~1800~~ 1600

Ron Schwadron, Ph.D.

Primary Examiner

Art Unit 1644